

I CLAIM:

1. A biopsy device suitable for collection of a tissue sample from a biopsy site in a body lumen, the biopsy device comprising:

an introducer assembly comprising a hollow sheath having a distal end portion and a proximal end portion, and the distal end portion of the introducer sheath defining at least one side aperture for receiving a tissue mass;

a cutter assembly comprising a hollow cutter tube having a distal end portion and a proximal end portion, the cutter tube being sized to be slidably received within and extend axially through the introducer sheath, and the distal end portion of the cutter tube including at least one cutting edge;

an endoscope assembly including a fiber optic bundle for viewing the biopsy site, the bundle being sized to be received within and extend axially through the cutter tube; and

the cutter tube and the introducer sheath cooperating to sever the tissue sample by relative movement therebetween.

2. The biopsy device of claim 1, wherein the distal end portion of the cutter tube further defines a notch.

3. The biopsy device of claim 2, wherein the distal end portion of the cutter tube is rotatable relative to the introducer distal end portion.

4. The biopsy device of claim 2, wherein the introducer distal end portion is rotatable relative to the distal end portion of the cutter tube.

5. The biopsy device of claim 1, wherein the distal end portion of the cutter tube includes a cutter aperture.

6. The biopsy device of claim 5, wherein the distal end portion of the cutter tube is rotatable relative to the introducer distal end portion.

7. The biopsy device of claim 5, wherein the introducer distal end portion is rotatable relative to the distal end portion of the cutter tube.

8. The biopsy device of claim 5, wherein the distal end portion of the cutter tube is axially reciprocable relative to the introducer distal end portion.

9. The biopsy device of claim 5, wherein the cutter aperture further includes a barbed portion.

10. The biopsy device of claim 1, wherein the distal end portion of the cutter tube includes a cutting edge.

11. The biopsy device of claim 10, wherein the distal end portion of the cutter tube is extendable past the distal end of the introducer.

5 12. The biopsy device of claim 11, wherein the cutter tube is rotatable.

13. The biopsy device of claim 10, wherein the introducer sheath at the distal end portion thereof defines an introducer reservoir.

10 14. The biopsy device of claim 1, wherein the cutter tube and the endoscope assembly define a liquid passageway.

15. The biopsy device of claim 1, wherein the introducer hollow sheath inner diameter is about 0.001 inches to about 0.1 inches greater than the outer diameter of the cutter tube.

15 16. The biopsy device of claim 1, wherein the introducer hollow sheath inner diameter is about 0.0002 inches to about 0.001 inches greater than the outer diameter of the cutter tube.

17. The biopsy device of claim 1, wherein the introducer side aperture has an axial length of about 1 millimeter to about 5 millimeters.

20 18. The biopsy device of claim 1, wherein the introducer side aperture has an axial length of about 2 millimeter to about 3 millimeters.

19. The biopsy device of claim 1, wherein the introducer side aperture extends over about one-half the introducer hollow sheath circumference.

20. The biopsy device of claim 1, wherein the introducer distal end portion includes an open end.

25 21. The biopsy device of claim 1, wherein the introducer distal end portion includes a plurality of side apertures.

22. The biopsy device of claim 1, wherein the cutting edge is provided with crenations.

30 23. A biopsy device suitable for collection of a tissue sample from a biopsy site in a body lumen, the biopsy device comprising:

an introducer assembly, a cutter assembly slidably received within the introducer assembly, and an endoscope assembly situated within the cutter assembly;

the introducer assembly comprising a tubular sheath having a distal end portion that defines a side aperture for receiving the tissue sample;

5 the cutter assembly comprising a hollow cylindrical cutter having a distal end portion, the cutter being co-axial with the introducer sheath and having a lesser outside diameter than the introducer sheath inside diameter, the cylindrical cutter including at least one cutting edge;

the endoscope assembly comprising a fiber optic bundle, the fiber optic bundle being co-axial with the hollow cutter and having a lesser outside diameter than the cutter inside diameter; and

10 at least the introducer distal end portion and the cutter distal end portion being mounted for movement relative to one another, the relative movement of the cutter distal end portion and the distal end portion of the tubular sheath causing the cutting of the tissue sample received therebetween.

15 24. The biopsy device of claim 23, wherein the distal end portion of the cylindrical cutter further defines a notch.

25. The biopsy device of claim 24, wherein the distal end portion of the cylindrical cutter is rotatable relative to the sheath distal end portion.

26. The biopsy device of claim 24, wherein the sheath distal end portion is rotatable relative to the distal end portion of the cylindrical cutter.

20 27. The biopsy device of claim 23, wherein the distal end portion of the cylindrical cutter includes a cutter aperture.

28. The biopsy device of claim 27, wherein the distal end portion of the cylindrical cutter is rotatable relative to the sheath distal end portion.

25 29. The biopsy device of claim 27, wherein the sheath distal end portion is rotatable relative to the distal end portion of the cylindrical cutter.

30. The biopsy device of claim 27, wherein the distal end portion of the cylindrical cutter is axially reciprocable relative to the sheath distal end portion.

30 31. The biopsy device of claim 27, wherein the cutter aperture further includes a barbed portion.

32. The biopsy device of claim 23, wherein the distal end portion of the cylindrical cutter includes a cutting edge.

33. The biopsy device of claim 32, wherein the distal end portion of the cylindrical cutter is extendable past the distal end of the sheath.

34. The biopsy device of claim 33, wherein the cylindrical cutter is rotatable.

5 35. The biopsy device of claim 32, wherein the sheath at the distal end portion thereof defines an introducer reservoir.

36. The biopsy device of claim 23, wherein the cylindrical cutter and the endoscope assembly define a liquid passageway.

10 37. The biopsy device of claim 23, wherein the sheath inner diameter is about 0.001 inches to about 0.1 inches greater than the outer diameter of the cylindrical cutter.

38. The biopsy device of claim 23, wherein the sheath inner diameter is about 0.0002 inches to about 0.001 inches greater than the outer diameter of the cylindrical cutter.

15 39. The biopsy device of claim 23, wherein the introducer side aperture has an axial length of about 1 millimeter to about 5 millimeters.

40. The biopsy device of claim 23, wherein the introducer side aperture has an axial length of about 2 millimeter to about 3 millimeters.

20 41. The biopsy device of claim 23, wherein the introducer side aperture extends over about one-half the sheath circumference.

42. The biopsy device of claim 23, wherein the sheath distal end portion includes an open end.

43. The biopsy device of claim 23, wherein the sheath distal end portion includes a plurality of side apertures.

25 44. The biopsy device of claim 23, wherein the cutting edge is provided with crenations.

η

30 45. A biopsy device suitable for collection of a tissue sample from a biopsy site in a body lumen, the biopsy device comprising an introducer assembly having an introducer distal end portion, a cutter assembly within the introducer assembly and having a cutter distal end portion, and an endoscope within the cutter assembly and having a fiber optic bundle distal end portion;

a working end portion of the biopsy device comprising the introducer distal end portion, the cutter distal end portion, and the fiber optic bundle distal end portion;

5 the introducer distal end portion having a tubular configuration and defining at least one side aperture;

the cutter distal end portion having a tubular configuration and including a cutting edge;

10 the cutter distal end portion being slidably received within the introducer distal end portion and the fiber optic bundle distal end portion being received inserted within the cutter distal end portion, and

the cutter distal end portion coacting with the introducer distal end portion to cut the tissue sample.

46. The biopsy device of claim 45, wherein the cutter distal end portion further defines a notch.

15 47. The biopsy device of claim 46, wherein the cutter distal end portion is rotatable relative to the introducer distal end portion.

48. The biopsy device of claim 46, wherein the introducer distal end portion is rotatable relative to the cutter distal end portion.

20 49. The biopsy device of claim 45, wherein the cutter distal end portion further includes a cutter aperture.

50. The biopsy device of claim 49, wherein the cutter distal end portion is rotatable relative to the introducer distal end portion.

51. The biopsy device of claim 49, wherein the introducer distal end portion is rotatable relative to the cutter distal end portion.

25 52. The biopsy device of claim 49, wherein the cutter distal end portion is axially reciprocable relative to the introducer distal end portion.

53. The biopsy device of claim 49, wherein the cutter aperture further includes a barbed portion.

30 54. The biopsy device of claim 45, wherein the cutter distal end portion includes a cutting edge.

55. The biopsy device of claim 54, wherein the cutter distal end portion is extendable past the introducer distal end portion.

56. The biopsy device of claim 55, wherein the cutter distal end portion is rotatable.

57. The biopsy device of claim 54, wherein the introducer distal end portion includes an introducer reservoir.

5 58. The biopsy device of claim 45, wherein the cutter distal end portion and the endoscope assembly define a passageway.

59. The biopsy device of claim 45, wherein the introducer distal end portion is about 0.001 inches to about 0.1 inches greater less than the outer diameter of the cutter distal end portion.

10 60. The biopsy device of claim 45, wherein the introducer distal end portion has an inner diameter about 0.0002 inches to about 0.001 inches greater than the outer diameter of the cutter distal end portion.

61. The biopsy device of claim 45, wherein the introducer side aperture has an axial length of about 1 millimeter to about 5 millimeters.

15 62. The biopsy device of claim 45, wherein the introducer side aperture has an axial length of about 2 millimeter to about 3 millimeters.

63. The biopsy device of claim 45, wherein the introducer side aperture extends over about one-half the introducer distal end portion circumference.

20 64. The biopsy device of claim 45, wherein the introducer distal end portion includes an open end.

65. The biopsy device of claim 45, wherein the introducer distal end portion includes a plurality of side apertures.

25 66. The biopsy device of claim 45, wherein the cutting edge further includes crenations.